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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,828	10/29/2001	Yongming Sun	DEX-0247	6752
26259	7390	03/23/2004	EXAMINER	
LICATLA & TYRRELL P.C.			LY, CHEYNE D	
66 E. MAIN STREET			ART UNIT	
MARLTON, NJ 08053			PAPER NUMBER	
			1631	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

2/27

Office Action Summary	Application No. 10/082,828	Applicant(s) SUN ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 07, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed January 07, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The amendment to the specification has been acknowledged.
3. The cancellation of claims 6, and 9-17 has been acknowledged.
4. Claims 1-5, 7, and 8, SEQ ID NO. 75, are examined on the merits.

Claims Rejected Under U.S.C. § 112, First Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
7. This rejection is necessitated by amendment.

RESPONSE TO ARGUMENT

8. Applicant argues by amending claim 1 to recite the limitation of "a nucleic acid molecule having at least 85% sequence identity the nucleic acid molecule of (a) or (b)"; and citing the instant specification which supports that Applicant is in possession of the sequence of SEQ

ID NO. 75, and molecules having at least 85% identity to the sequence of SEQ ID NO. 75.

Applicant's argument and pointed to disclosure in the instant specification have been fully considered and found to be unpersuasive as discussed below.

9. The amended limitation "a nucleic acid molecule having at least 85% sequence identity to the nucleic acid molecule of (a) or (b)" does not help Applicant overcome the instant Lack of Written Description rejection because the amended limitation has only changed to the percent identity criteria from 60% to 85%. However, the amended claims have not changed the breadth of the claimed invention, which encompasses sequences beyond that of SEQ ID No. 75, which are not fully supported by the instant specification on written description basis. It is acknowledged there is written description basis for the sequence of SEQ ID No. 75 and the criteria of at least 85% identity; however, the instant specification falls short of disclosing, beyond the sequence of SEQ ID NO. 75, the different permutation of nucleic sequences having at least at least 85% identity with the sequence of SEQ ID No. 75. Further, the limitation of sequences with less than 85% identity, which are breast specific nucleic acid species of sequence, does not have written description basis. One of skill in the art cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

REJECTION RE-ITERATED

10. The specification discloses SEQ ID NO: 75. Claims 1-5, 7, and 8 are directed to sequences, which encompass sequences having at least 85% sequence identity to sequence of

Art Unit: 1631

SEQ ID NO. 75. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

11. With the exception of SEQ ID NO: 75, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that: "...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

12. Therefore, only SEQ ID NO: 75 but not the full breadth of the claims 1-5, 7, and 8 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant

Art Unit: 1631

is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 3-5, 7, and 8 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Birren et al. (May 2000).

15. This rejection is maintained with respect to claims 1, 3-5, 7, and 8, as recited in the previous office action mailed August 07, 2003.

16. This rejection is necessitated by amendment.

RESPONSE TO ARGUMENT

17. Applicant argues by amendment to have claim 1 recite the critical limitation of “a nucleic acid molecule having at least 85% sequence identity the nucleic acid molecule of (a) or (b)” which has been fully considered and found to be unpersuasive as discussed below.

18. The amended limitation of “a nucleic acid molecule having at least 85% sequence identity the nucleic acid molecule of (a) or (b)” does not help Applicant overcome the prior art of Birren et al. because Birren et al. discloses a sequence that has at least 85% sequence identity to the nucleic acid molecule of (a) or (b) (Result 1, Best Local Similarity 97.1%).

The 97.1% identity of the sequence of Birren et al. to that of SEQ ID NO. 75 clearly anticipates said critical limitation of the instant claimed invention.

REJECTION RE-ITERATED

19. Birren et al. discloses a nucleic acid molecule (Accession Number AC024983) that is at least 85% (Best Local Similarity 97.1%) sequence identity to the nucleic acid molecule of SEQ ID NO. 75. Further, the nucleic acid of Birren et al. is of human genomic DNA in a M13 vector (page 1, lines 7 and 51; and page 2, line 46), as in instant claims 1, 3-5, 7, and 8. It is well known in the art that the M13 vector is propagated in bacterial host cells (Griffiths et al., page 3, lines 8-13).

CONCLUSION

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

21. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices

Art Unit: 1631

published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

25. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

C. Dune Ly
3/22/04

Justin H. Woodward
3/22/04